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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,171	01/17/2002	Kai-Uwe Lewandrowski	CSI 126	4535

23579 7590 01/08/2007

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ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	01/08/2007	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/054,171
Filing Date: January 17, 2002
Appellant(s): LEWANDROWSKI ET AL.

PATREA PABST
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 30, 2005 appealing from the Office action mailed July 1, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

WO 00/13024 FINDLAY ET AL. 03-2000

NAIR, S.P. et al. "Molecular Chaperones Stimulate Bone Resorption", Calcified Tissue Int. (1999) 64, pages 214-218.

REDDI, K. et al. "The Escherichia coli chaperonin 60 (groEL) is a potent stimulator of osteoclast formation", J. of Bone and Mineral Research, Vol. 13, No. 8, 1998, pages 1260-1266.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of osteoporosis caused by bacterial infection, does not reasonably provide enablement for detecting osteoporosis by measuring concentration of other types of pathogens such as viruses, viral produced factors, protozoa, protozoal produced factors, parasites, parasitic produced factors, fungi, and fungal produced factors, as recited in instant claims 12, and 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The enablement test requires require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See MPEP § 2164.01, reciting In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). To determine whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement

and whether any necessary experimentation is "undue", following factors are considered: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, at 737

In this case, the scope of the claims is broader than the disclosure in the specification. The efficacy of the invention is unpredictable because of the wide variety of pathogens known to a skilled artisan. No direction or guidance, or working example is given by the inventors with respect to the recited pathogens in claims 12 and 13.

Applicants assert that "assays for infectious agents, factors produced by infectious agents and heat shock proteins are also routine." Applicants' argument is not persuasive because the issue here is not whether general method of assays for infectious agents or factors produced by thereof is enabling; the issue is whether the applicants' disclosure enables the claimed method of screening osteoporosis by running assays for the genus of the infectious agents, factors produced by thereof, and heat shock proteins as recited. For example, the Nair reference teaches that not all bacterial molecular chaperones stimulate bone resorption. Thus one skilled in the art would find it unpredictable to make/use the claimed invention as disclosed. Undue experimentation is required to test the efficacy of the claimed invention and the disclosure is not enabling the skilled artisan with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-6, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findlay (WO00/13024) in view of Nair (Calcif. Tissue Int., vol. 64, no. 3, Mar. 1999).

Findlay teaches the method of diagnosing osteroporosis or osteroarthritis by detecting biochemical markers. See p. 3, line 22 – p. 4. The invention includes method steps of taking bone sample and measure or estimate the level of the marker of bone remodeling in the sample by extracting mRNA from the sample, estimating the level of expression for the makers by measuring the quantity of mRNA specific for that marker, and comparing the level to a standard. While the reference teaches using markers associated with bone resorption, the reference fails to teach using the pathogens or heat shock proteins as required by the instant invention. See p. 4, line 16 – p. 5, line25.

Nair teaches that molecular chaperones (heat shock proteins) stimulate bone resorption. See abstract. The reference teaches that HSP 70 is capable of inducing osteolysis. See p. 217, second column, last par. P. 218, first column, last par. While applicants assert that the claimed invention is directed to HSP's that are "induced in response to an infectious agents", examiner notes Nair also teaches that "the molecular chaperones released by bacteria may play a role in the pathology of bone infections". See p. 218, first full par. The reference goes on to state, "the finding that mammalian

molecular chaperones can also induce calvarial breakdown raises the possibility that release of these conditions not involving bacterial infection."

Given the general teaching in Findley that the method of detection of osteoporosis by screening the concentration of markers associated with bone resorption, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Nair for specific types of markers that also stimulate bone resorption.

2. Claims 1, 12-14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findley in view of Reddi et al. (J. Bone and Mineral Res., v. 13, no. 8, Aug. 1998) ("Reddi").

Findley, discussed above, fails to teach the specific markers used in the instant invention.

Reddi teaches that the E. coli chaperonin 60 (groEL) stimulates bone resorption and osteoclast formation. See abstract. The reference suggests that bacterial cpn60s may play a role in the osteolysis associated with bone infections. The reference teaches that Antinobacillus actinomycetemcomitans causes periodontal bone loss and contains a potent bone-resorbing protein, which is also found in cpn60 of E. coli. See p. 1260, col. 2, bridging paragraph. The reference suggests the possibility that bacterial infection of the chaperonins could be responsible for bone infection diseases such as osteoporosis. See p.1265, col. 1, bridging paragraph.

Given the general teaching in Findley that the method of detection of osteoporosis by screening the concentration of markers associated with bone resorption, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to have looked to the prior arts such as Reddi for specific types of markers that also stimulate bone resorption.

(10) Response to Argument

Examiner notes that claims 3-11 and 14-19 are inadvertently included in the enablement rejection made under 35 U.S.C. § 112, first paragraph.

It is also noted that claim 10 is also inadvertently omitted in rejection made under 35 U.S.C. 103(a). In the body of discussion of Findlay the method of detecting osteoporosis using an immunoassay with body fluid has been discussed.

Claims 7, 9, and 15-18 are free of prior art and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Enablement rejection on claims 1, 2, 12, 13 should be maintained.

In analysis of Wand's factors, appellants assert that the method of detecting osteoporosis by assaying bone related tissue or cell, and assaying the concentration of a marker is well known. Appellants rephrase the examiner's obviousness rejection by stating, "examiner admits . . . that general methods for obtaining a sample of bone related tissue or cells from an individual ; of assaying the concentration of infectious agents or factors produced by infectious agents or heat shock proteins produced in response to infectious agents . . are well known in the art". The statement is incorrect, since the 103 rejection is made on the basis that the skilled artisan would have looked to the prior arts for "specific" types of markers that stimulate bone resorption. Examiner's obviousness rejection does not indicate obviousness of using all genuses of

infectious agents or factors and heat shock protein produced by infectious agents to detect osteoporosis.

Examiner disagrees with appellants' conclusion that quantity of experimentation to perform the method is minimal. As indicated in the rejection, the scope of the claim is broader than the enabled invention because the claim encompasses using entire class of infectious agents and factors/proteins caused by infectious agents. Appellants assert that the specification on pages 34, 39-40, and 31-32 provides enablement for using certain parasites, protozoans, and viruses as a marker in detection of osteoporosis. However, the disclosure does not teach whether these are associated with osteoporosis, and there is no evidence for a skilled artisan to believe that all types of infectious agents are useful in detecting the disease. As indicated in the rejection, the class of pathogens known to a skilled artisan is enormous, thus having to determine the efficacy of all the species of the claimed range would require undue experimentation to a skilled artisan.

Appellants assert that it is not understood why the teaching of Nair that not all bacterial molecular chaperones stimulate bone resorption has anything to do with the method of detecting osteoporosis as presently claimed. In this context, the reference implies that not every type of infectious agent or a factor produced by an infectious agent will indicate the skeletal disorder in an individual. In view of the teaching of Nair. And thus a skilled artisan would not have believed that all types of infectious agents and factors produced thereby would detect the disease. Examiner asserts that in view of these factors, appellants' disclosure does not enable the scope of the claimed invention.

Claims 1-6, 8, 10, and 11 are properly rejected under 35 U.S.C. § 103 (a) as unpatentable over Findlay in view of Nair.

Appellants argue that Nair is not related to osteoporosis. Examiner disagrees, because Nair teaches that molecular chaperones (heat shock proteins) stimulate bone resorption, and HSP 70 in particular is capable of inducing osteolysis. See abstract; p. 217, second column, last par. P. 218, first column, last par. Findlay teaches that osteoporosis is a bone disorder whereby the bone balance of remodeling is skewed in the favor of bone loss. See Findlay, p. 6, lines 19 – 25.

Given the knowledge that unbalanced bone resorption or bone loss causes osteoporosis, it would have been obvious to a skilled artisan that the disturbance of the balance of the bone density or mass, or the cause thereof, such as those taught by Nair, would be an indication of the bone disease.

Claims 1, 12-14, and 19 are properly made under 35 U.S.C. § 103 (a) as unpatentable over Findlay in view of Reddi.

Appellants assert that Reddi does not relate to osteoporosis. Examiner respectfully disagrees. The reference teaches that bacterial cpn60s have resorptive activity and stimulates osteoclast, which, in turn causes loss of bone density. Findlay provides that unbalanced bone density causes bone diseases such as osteoporosis. Given the combined teachings of the references, it would have been obvious to a skilled artisan that skeletal diseases such as osteoporosis and the resorptive activity of bacterial cpn60s are related. Regarding the remark in the abstract that it is possible that endogenous chaperonins may have a role in other bone loss disorders, such as osteoporosis, appellants describe it as evidence that the prior art is distinct from studies

involving osteoporosis. Examiner views that the remark in the abstract is a literal suggestion that the bone resorption caused by the chaperonins may be also related to osteoporosis, providing a motivation for the skilled artisan to practice the claimed invention.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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SUPERVISORY PATENT EXAMINER

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